

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application)	<u>PATENT APPLICATION</u>
)	
Inventor(s): Heller, Jonathan C., et al.)	
)	Art Unit: Unassigned
Application No.: Unassigned)	
)	Examiner: Unassigned
Filed: Herewith)	
)	
Title: Assay Customization)	
)	

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Listed below or on an attached Form PTO-1449 is information known to applicant(s). A copy of each listed publication and U.S. and foreign patent, except for pending U.S. applications, is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. If form PTO-1449 is enclosed, the Examiner is requested to initial and return it in accordance with MPEP §609.

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56.

- ☒ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because (check all that apply):
- ☒ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage
-- OR --
- ☐ (3) It is being filed before the mail date of the first Office Action on the merits
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- ☐ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- ☐ a certification as specified in §1.97(e) is provided below; **or**
- ☐ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
- B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**
- C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☒ In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No. 10/645,863 filed 8/20/2003), copies are not enclosed herewith.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
- ☒ Copies of only foreign patent documents and non-patent literature not cited in S/N 10/645,863 are enclosed in accordance with 37 CFR 1.98 (a)(2). (The US patents and each US patent appl. publ. listed on the attached Form PTO-1449 are not enclosed

because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i).

- ☐ There are no listed references which are not in the English language.
- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.
- ☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 29191.706.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

By: 


Vern Norviel, Reg. No. 32,483

Dated: January 16, 2004

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application No.	Unassigned
				Filing Date	Herewith
				First Named Inventor	Heller, Jonathan
				Art Unit	Unassigned
				Examiner Name	Unassigned
Sheet	1	Of	4	Attorney Docket No.	29191.706.201

U.S. PATENT DOCUMENTS					
Examiner's Initials	Cite No. ¹	Document No.	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US-6,068,749	5/30/00	Karger et al.	
		US-5,872,010	2/16/99	Karger et al.	
		US-5,917,184	6/29/99	Carson et al.	
		US-5,958,202	9/28/99	Regnier et al.	
		US-6,375,817	4/23/02	Taylor et al.	
		US-6,175,112	1/16/01	Karger et al.	
		US-6,342,142	1/29/02	Ramsey et al.	
		US-6,231,737	5/15/01	Ramsey et al.	
		US-6,033,546	3/7/00	Ramsey	
		US-6,358,692	3/19/02	Jindal et al.	
		US-5,856,671	1/5/99	Henion et al.	
		US-6,207,954	3/27/01	Andrien, Jr. et al.	
		US-6,139,734	10/31/00	Settlage, et al.	
		US-5,245,186	9/14/93	Chait et al.	
		US-5,045,694	9/3/91	Beavis et al.	
		US-4,977,320	12/11/90	Chowdhury et al.	
		US-6,318,970	11/20/01	Backhouse	
		US-6,368,562	4/9/02	Yao	
		US-5,993,633	11/30/99	Smith et al.	
		US-6,187,190	2/13/01	Smith et al.	
		US-6,107,628	8/22/00	Smith et al.	
		US-5,545,304	8/13/96	Smith et al.	
		US-5,833,861	11/10/98	Afeyan et al.	
		US-5,952,653	9/14/99	Covey et al.	
EXAMINER SIGNATURE			DATE CONSIDERED		

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		Number-Kind Code ² (if known)			
		US-5,393,975	2/28/95	Hail et al.	
		US-6,322,682	11/27/01	Arvidsson et al.	
		US-6,379,791	4/30/02	Schneider et al.	
		US-6,017,693	1/25/00	Yates III, et al.	
		US-4,483,885	11/20/84	Chait et al.	
		US-4,443,319	4/17/84	Chait et al.	
		US-5,599,432	2/4/97	Manz et al.	
		US-5,296,114	3/22/94	Manz	
		US-6,086,243	7/11/00	Paul et al.	
		US-6,091,502	7/18/00	Weigl et al.	
		US-6,159,739	12/12/00	Weigl et al.	
		US-6,277,641	8/21/01	Yager	
		US-5,624,539	4/29/97	Ewing et al.	
		US-5,358,618	10/25/94	Ewing et al.	
		US-6,284,113	9/4/01	Bjornson et al.	
		US-6,280,589	8/28/01	Manz et al.	
		US-6,240,790	6/5/01	Swedberg et al.	
		US-6,284,115	9/4/01	Apffel	
		US-2002/0039747	4/4/02	Lubman et al.	
		US-2002/0054289	5/9/02	Thibault et al.	
		US-2002/0036140	3/28/02	Manz et al.	
		US-2002/0041827	4/11/02	Yager et al.	
		US-2001/0014461	8/16/01	Hutchens et al.	
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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		WO 00/65472	11/2/00	Ringold et al.		
		WO 02/06829	1/24/02	Hitt et al.		
EXAMINER SIGNATURE				DATE CONSIDERED		

OTHER PRIOR ART - NON PATENT RELATED DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published		T ²
		ADAM, Bao-Ling, et al. "Serum protein fingerprinting coupled with a pattern-matching algorithm distinguishes prostate cancer from benign prostate hyperplasia and healthy men". <i>Cancer Research</i> , (2002) 62:3609-3614.		
		BERTERO, M., "Linear inverse and ill-posed problems". <i>In Advances in Electronics and Electronic Physics. Academic Press</i> , (1989), NY.		
		CHEN, S.S. et al. "Atomic decomposition by basis pursuit". <i>SIAM Journal on Scientific Computing</i> , (1988), 20(1):33-61.		
		COVEY, Thomas R., et al. "Structural Characterization of Protein Tryptic Peptides via Liquid Chromatography/Mass Spectrometry and Collision-Induced Dissociation of Their Doubly Charged Molecular Ions". <i>Anal. Chem.</i> , (1991), 63:1193-1200		
		DONOHO, D. L. "Nonlinear solution of linear inverse problems by wavelet-vaguelette decomposition". <i>App. and Comp. Harmonic Analysis</i> , (1995), 2:101-126.		
		DONOHO, D. L. "Unconditional bases are optimal bases for data compression and for statistical estimation". <i>Applied and Computational Harmonic Analysis</i> , (1993), 1(1):100-115.		
		DONOHO, D. L., et al. "Adapting to unknown smoothness via wavelet shrinkage". <i>Journal of the American Statistical Association</i> , (1995), 90(432):1200-1224.		
		GUYON, I, et al. "An introduction to variable and feature selection". <i>JMLR</i> , (2003), 1:1-48.		
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Sheet	4	Of	4	Attorney Docket No.	29191.706.201

OTHER PRIOR ART – NON PATENT RELATED DOCUMENTS			
		HAYES, Roger N., et al. "Collision-Induced Dissociation". <i>Methods in Enzymology</i> , (1990), Vol. 193, pages 237-263	
		KALIFA, Jerome, et al. "Minimax Deconvolution in Mirror Wavelet Bases". <i>IEEE Trans. on Image Processing</i> . (1999), 1-30.	
		KALIFA, Jerome, et al. "Thresholding Estimators for Linear Inverse Problems and Deconvolutions". <i>Annals of Statistics</i> (2003), no. 1, 58-109.	
		LIOTTA, Lance, A., et al., "Written in Blood". <i>Nature</i> , (10/30/2003), Volume 425, Page 905.	
		PETRICOIN III, E. F., et al., "Serum proteomic patterns for detection of prostate cancer". <i>JNCI</i> , (2002), 94(20):1576-1578.	
		PETRICOIN III, E. F., et al., "Use of proteomic patterns in serum to identify ovarian cancer". <i>The Lancet</i> , (2002), 359:572-577.	
		SERVICE, R.F., "Recruiting genes, proteins for a revolution in diagnostics". <i>Science</i> , (4/11/03), 300:236-239	
		STRAND, O. N. "Theory and methods related to the singular function expansion and landweber's iteration for integral equations of the first kind". <i>SIAM J. Num. Anal.</i> , (1973), 5.	
		STRITTMATTER, E. F., et al., "High mass measurement accuracy determination for proteomics using multivariate regression fitting: application to electrospray ionization time-of-flight mass spectrometry". <i>Anal. Chem.</i> , (2003), 75(3):460-468.	
		TIBSHIRANI, Robert "Regression shrinkage and selection via the lasso". <i>J. Royal Statist. Soc.</i> , (1996), 58:267-288.	
		TIKHONOV, A. N. "Solution of incorrectly formulated problems and the regularization method". <i>Soviet Math. Doklady</i> , (1963), 4:1035-1038.	
		TIRUMALAI, Radhakrishna S., et al. "Characterization of the Low Molecular Weight Human Serum Proteome". <i>Molecular & Cellular Proteomics</i> 2.10, (8/13/2003), Pages 1096-1103.	
		VESTAL, M., et al. "Resolution and Mass Accuracy in Matrix-Assisted Laser Desorption Ionization-Time-of-Flight", <i>J. Am. Soc. Mass Spectrom.</i> , (1998), 9, 892-911	
		WEHOFSKY, M., et al. "Automated deconvolution and deisotoping of electrospray mass spectra". <i>J. Mass Spectrom.</i> , (2002), 37(2):223-229.	
		WEHOFSKY, M., et al. "Isotopic deconvolution of matrix-assisted laser desorption/ionization mass spectra for substance class specific analysis of complex samples", (2001), 7:39-46.	
		WILLIAMS, Jon, D. et al. "Using accurate mass electrospray ionization time-of-flight mass spectrometry with in-source collision-induced dissociation to sequence peptide mixtures". <i>Journal of Chromatography A</i> , (2003) 1020:11-26	
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